IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

LORI COMBS,	)	CASE NO. 1:18 CV 802
	)	
Plaintiff,	)	JUDGE DONALD C. NUGENT
	)	
v.	)	
	)	
BAYER HEALTHCARE PHARMACEUTICALS INC., *et al.*,	)	MEMORANDUM OPINION AND ORDER
	)	
Defendants.	)	

This matter is before the Court on the Motion of Defendants Bayer Healthcare Pharmaceuticals Inc., Bayer Corporation and Bayer HealthCare LLC (collectively "Bayer") to Dismiss the Amended Complaint pursuant to Fed. R. Civ. P. 12(b)(6). (ECF #54) Plaintiff has filed a brief in opposition and Defendants have filed a brief in reply. The Court heard oral argument on the Motion and permitted the parties to file supplemental briefs. The motion is now ready for decision.

FACTS[1]

Plaintiff Lori Combs filed her original Complaint in the United States District Court of the Northern District of California on November 1, 2017. The action was transferred to this Court on April 10, 2018. Plaintiff filed an amended complaint on November 19, 2018, asserting claims of negligence, strict liability, breach of warranty and statutory product liability claims under Ohio

---

1 The factual allegations are taken from the Plaintiff's Complaint and will be accepted as true for the purposes of this motion. In addition, judicial notice will be taken of documents on the FDA's website as matters of public record. *See Reeves v. PharmaJet, Inc.*, 846 F.Supp.2d 791, 794 n.1 (N.D. Ohio 2012).

Rev. Code §§ 2307.71 - 2307.80. This Court has jurisdiction based on diversity of citizenship, 29 U.S.C. § 1332.

Ms. Combs asserts that she was injected with the linear gadolinium-based contrast agent ("GBCA") Magnevist prior to receiving MRIs on or around January, 2006. (ECF #49, ¶12) Bayer manufactures, tests, markets, advertises, and sells the linear GBCA Magnevist.(Id. ¶16) Thereafter, Plaintiff states that she suffered gadolinium retention in multiple organs and soft tissues (e.g., brain, heart, liver, kidney, bones and skin). Ms. Combs also asserts that gadolinium, a toxic heavy metal, caused fibrosis in Plaintiff's organs, bone, and skin, as well as other adverse reactions and crossed the blood-brain barrier and deposited in the neuronal nuclei of her brain.(Id. ¶ 14) Plaintiff states that she continues to have retained gadolinium in her body many years after being administered Magnevist in 2006, resulting in permanent physical and emotional injuries.(Id. ¶13) Plaintiff contends that she did not realize the connection between her use of linear GBCAs and her injuries until on or around June 2016, (Id.) However, Plaintiff appeared before an FDA Medical Imaging Drugs Advisory Committee on September 8, 2017, where she told the Committee "I am one of those elusive humans, one who has normal renal function, yet has retained gadolinium from a single dose of Bayer's Magnevist for over a decade. I've been exhibiting and reporting clinical symptoms the entire time....I've personally been reporting my symptoms since 2006 to the FDA, to Bayer, and to multiple researchers, and every single one of you has refused to listen." (ECF 54, Ex. 6)

STANDARD OF REVIEW

In evaluating a motion to dismiss, the court must construe the complaint in the light most favorable to the plaintiff, accept its factual allegations as true, and draw reasonable inferences in

favor of the plaintiff. *See Directv, Inc. v. Treesh*, 487 F.3d 471, 476 (6th Cir. 2007). The complaint need not contain detailed factual allegations, but it must include more than labels, conclusions, and formulaic recitations of the elements of a cause of action. *Id.* "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Ashcroft v. Iqbal,* 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009) (*citing Bell Atl. Corp. v Twombly,* 550 U.S. 544, 555 (2007)).

While Fed. R. Civ. P. 8(a)(2) requires a pleading to contain a "short and plain statement of the claim showing that the pleader is entitled to relief," to survive a motion to dismiss under Rule 12(b)(6), a complaint must allege facts that "state a claim to relief that is plausible on its face," and that, if accepted as true, are sufficient to "raise a right to relief above the speculative level." *Twombly,* 550 U.S. at 555, 570. "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Iqbal,* 556 U.S. 678. "A claim is plausible on its face if the 'plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.' " *Ctr. for Bio–Ethical Reform, Inc. v. Napolitano,* 648 F.3d 365, 369 (6th Cir.2011), *cert. denied,* 132 S.Ct. 1583, (2012) (quoting *Iqbal,* 556 U.S. at 677).

On a motion brought under Rule 12(b)(6), the court's inquiry is limited to the content of the complaint, although matters of public record, orders, items appearing in the record of the case, and exhibits attached to the complaint may also be taken into account. *See Bassett v. Nat'l Collegiate Athletic Ass'n,* 528 F.3d 426, 430 (6th Cir. 2008); *Amini v. Oberlin College*, 259 F.3d 493, 502 (6th Cir. 2001).

Thus, for the purposes of this Motion to Dismiss, the Court accepts the Plaintiff's factual

allegations as true and construes the Complaint in the light most favorable to Plaintiff. However, the Court will not credit the Complaint's mere conclusory statements without reference to its factual content. *Iqbal,* 566 U.S. at 686.

DISCUSSION

Bayer moves to dismiss the amended complaint asserting that Plaintiff's claims are (1) barred by Ohio's Statute of Limitations, (2) as pled, Plaintiff's claims are preempted, (3) Plaintiff's claims of Negligence, Strict Liability and Breach of Warranty are barred by Ohio's Product Liability Act, and (4) Plaintiff's claims under Ohio's Product Liability Act fail to meet the federal pleading standards. These arguments will be addressed in order as necessary.

Statute of Limitations

Defendants assert that Ohio's Statute of Limitations bars Plaintiff's claims. The applicable statute of limitations is Ohio Rev. Code § 2305.10(A) which provides that "an action based on a product liability claim and an action for bodily injury shall be brought within two years after the cause of action accrues." A "cause of action for bodily injury ... that is caused by exposure to hazardous or toxic chemicals, ethical drugs, or ethical medical devices accrues upon the date on which the plaintiff is informed by competent medical authority that the plaintiff has an injury that is related to the exposure, or upon the date on which by the exercise of reasonable diligence the plaintiff should have known that the plaintiff has an injury that is related to the exposure, whichever date occurs first." Ohio Rev. Code § 2305.10 (B)(1)(A)(emphasis added).

Defendants argue that Plaintiff's statement to the FDA Medical Imaging Drugs Advisory Committee where she asserted that:

> "I am one of those elusive humans, one who has normal renal function, yet has retained gadolinium from a single dose of Bayer's Magnevist for over a decade. I've been exhibiting and reporting clinical symptoms the entire time....I've personally been reporting my symptoms since 2006 to the FDA, to Bayer, and to multiple researchers, and every single one of you has refused to listen." (ECF #54, Ex. F)

shows that Plaintiff knew that her symptoms were related to her exposure to Magnevist when she began reporting symptoms in 2006. Thus, her claims accrued under the Ohio Statute in 2006 when Plaintiff "should have known that [she] had an injury that is related to the exposure" to Magnevist. As this action was filed in 2017, more than ten years after her claims accrued, the claims are time barred.

In her Amended Complaint, Plaintiff simply alleges without explanation or detail that she "did not realize the connection between her use of linear GBCAs and her injuries until on or around June 2016." (ECF #49, ¶13) However, Plaintiff's statements to the FDA Advisory Committee reflect that she had tied her symptoms to her exposure to Magnevist from the time of exposure in 2006 when she began reporting her symptoms to Bayer and the FDA. In her Opposition to Defendants' Motion to Dismiss, Plaintiff merely reiterates her allegation regarding first realizing the connection in June 2016, and contends that Defendants are "estopped from asserting a statute of limitations defense because of their concealment of the true character, quality, and nature of their linear GBCAs." (ECF #55 at 9) Specifically, Plaintiff states that Defendants did not publicly acknowledge the possibility of gadolinium retention in people with normal renal function until May 2018, thus, lay people like Plaintiff should not "ought to have known that ...gadolinium was retained in her body and that it was the source of her ailments." (Id.) Regardless of whether a "lay person" should have known that her ailments were related to

the exposure to Magnevist, Plaintiff here has clearly attributed her ailments to her exposure to Magnevist since 2006 and could have filed suit at that time. By Plaintiff's own testimony, Defendants' alleged concealment did not prevent Plaintiff from recognizing the connection between her exposure to Magnevist and her symptoms or from filing suit. *See also McCualsky v. Appalachian Behavioral Healthcare*, 100 N.E.3d 1049, 1055 (Ohio Ct. App. 2017)("To invoke [estoppel] as a bar to statute of limitations defense . . . the plaintiff must be able to show the defendant's specific actions prevented the plaintiff from timely filing the lawsuit.")

Accordingly, the Court finds that Plaintiff's claims accrued in 2006 when she recognized her injury. As such, Plaintiff's products liability claims are now barred by Ohio Rev. Code § 2305.10(A)[2].

CONCLUSION

For the reasons set forth above, Defendants' Motion to Dismiss the Amended Complaint (ECF #54) is granted. This action is terminated.

IT IS SO ORDERED.

Donald C. Nugent

DONALD C. NUGENT
United States District Judge

DATED: May 15, 2019

---

2 Plaintiff conceded that her claims for negligence, strict product liability and breach of warranty are abrogated under the Ohio Products Liability Act.(ECF #55 at 18) Accordingly, those claims (Counts1-3) are dismissed.